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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,951	03/03/2004	Kurt Friedrich Brandstadt	DOC 0084 PA	1997

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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,951	BRANDSTADT ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-16 and 19-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-16, and 19-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 2, 3, 17, and 18 have been canceled. Claims 1, 4-16, and 19-32 are still at issue and are present for examination.

Applicants' arguments filed on 4/26/07, have been fully considered and are not deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 12 and 27 are objected to because of the following informalities: Claims 12 and 27 recite "wherein the reaction is conducted in … a solvent condition.". The word condition should be deleted. Appropriate correction is required.

Claims 1, 4-16, and 19-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of forming an organic siloxane by hydrolysis and condensation of an organic silane selected from trimethylethoxysilane, $(Me_3SiO(CH_2CH_2O)_4CH_3)$, 3-glycidopropyldimethylethoxysilane, 1,1-dimethyl-1-sila-2-oxacyclohexane, and methyltriethoxysilane with trypsin or by condensation of the corresponding organic silanols with trypsin, does not reasonably provide enablement for forming any organic compound by reacting any organic reactant or organic intermediate reactant as defined in claims 1, 16, 31, and 32

with any hydrolase selected from *Candida antarctica* lipase, *Candida antarctica* lipase B, *Rhizomucor miehei* lipase, wheat germ lipase, trypsin, papain, pepsin or a combination thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants argue that the specification in paragraphs 38-39 provides various examples of monofunctional and polyfunctional organic reactants that may be contacted with hydrolase enzymes to catalyze the formation of an organic molecule. Accordingly, the claims are commensurate in scope with the enablement provided by the specification. However, these paragraphs merely reiterate the large genus of organic reactants also recited in the claims for which the Office has already provided reasons that this genus is not commensurate in scope with the enabled invention. The specification provides evidence that most hydrolase enzymes tested did not catalyze the hydrolysis or condensation of any organic silane at all, despite testing several different enzymes (see particularly example 1). Furthermore, not only did most hydrolases tested not catalyze the instant reactions, there is clearly no unifying

characteristics present in the few that were successful that could be used for the selection of other suitable enzymes from the enormous number of known hydrolases (or even known proteases). In fact even different sources of trypsin had distinctly different abilities to catalyze the claimed reactions. Furthermore, the specification provides substantial evidence that trypsin will not catalyze the hydrolysis and/or condensation of most of the enormous number of organic silanes or corresponding silanols included in the scope of the claims showing successful reactions with only trimethylethoxysilane, ($Me_3SiO(CH_2CH_2O)_4CH_3$), 3-glycidopropyldimethylethoxysilane, 1,1-dimethyl-1-sila-2-oxacyclohexane, and methyltriethoxysilane and provides absolutely no evidence that any corresponding germanium containing compounds can be used. The group of successful reactants do not share any unifying characteristics with which a skilled artisan could reasonably predict what other organic silanes or corresponding silanols could be used. As there are virtually an infinite number of possible combinations of enzymes and organic reactants encompassed in the claims, the specification shows that the vast majority of combinations are unsuccessful, and the specification provides absolutely no guidance for the selection of others combinations which are successful, it would require undue experimentation to practice

the full scope of claimed methods. Applicants argue that there is no disclosure in any of the examples for which a hydrolase enzyme, as defined by the claims, was not able to catalyze the hydrolysis or condensation of an organic reactant. This is simply not true. Example 10 of the specification shows that phenyldimethylethoxysilane was hydrolysed but not condensed by trypsin, triphenylethoxysilane was neither hydrolysed nor condensed in the presence of trypsin, trypsin did not catalyze the condensation of heptamethylhydroxytetracyclosiloxane, and did not catalyze the polycondensation of a silicic acid precursor, tetraethoxysilane, and Example 11 shows that different sources of trypsin had different abilities to catalyze reactions with the same reactant. All other enzymes recited in the claims were tested only with trimethylsilanol but would be expected to have variability in their specificities as well. Furthermore, clearly the amount of activity even with trimethylsilanol present for pepsin and papain was very small and similarly to that found for chymotrypsin might well be due to contaminating amounts of trypsin in the protease preparation. As such clearly not even trypsin will hydrolyze/condense all organic reactants within the scope of the instant claims and the specification provides no guidance for selecting those that will be successful.

Claims 1, 4-16, and 19-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is explained in the previous Office Action.

Applicants argue that the claims and specification clearly disclose the organic reactants and hydrolase enzymes and the reaction sequences employed in the methods of the present invention. However, the disclosure of the specification for both the organic reactants and the hydrolases clearly encompass large genera of compounds/enzymes for which most combinations will be unsuccessful in the claimed methods. As discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination

of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Clearly in this case this has not been satisfied, as the specification documents that there is substantial variability within both genera and the specification provides no guidance concerning identifying characteristics of enzyme/organic reactant pairs which will be successful. As such the description is insufficient.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 9-16, 19-20, and 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Cha et al.

Cha et al. teach the formation of phenylsilsesquioxane from tetraethoxysilane using an enzymatic hydrolysis and condensation with the proteases trypsin, papain or silacatein in aqueous buffer at neutral pHs and temperatures of 20°C. As such Cha et al. anticipate all of the instant claims.

Applicants argue that Cha et al. discloses that trypsin and papain do not catalyze the polymerization of silica. Specifically, as set forth in Table 1 of Cha et al, papain and

trypsin report less reactivity with silica than the non-specific protein BSA control. In addition, as disclosed in Table 2 of the present application, the BSA control is also shown as not being able to catalyze the reaction as compared with the protease enzymes. However, this is not persuasive as both trypsin and papain show double the amount of polymerization present in the absence of any added protein. The fact that BSA also appeared to catalyze the reaction is irrelevant. Furthermore, applicants argument that BSA is shown in the specification as being unable to catalyze the reaction as compared to the proteases is not persuasive as the reactions are not the same. A different substrate was used by Cha et al. than used by applicants and there is substantial evidence that not every protein can catalyze the reaction with every substrate.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a),

the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 9-16, 20, and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedrich (WO02/22842) in view of the 1997 Sigma catalog.

Friedrich teaches the formation of organic siloxanes from a variety of organic silanes using an enzymatic hydrolysis and condensation with a lipase in aqueous or organic solvents at neutral pHs and temperatures of about 25°C. The organic silanes used included phenyltriethoxysilane and tetrabutoxysilane. Friedrich does not specifically teach using the lipases recited in the instant claims.

The 1997 Sigma catalog shows that the *Candida antarctica* lipase, *Rhizomucor miehei* lipase and wheat germ lipases are all well known commercially available lipases.

As Friedrich teaches the formation of organic siloxanes from a variety of organic silanes using an enzymatic hydrolysis and condensation with any lipase, it would have been obvious to one of ordinary skill in the art to select one of the commercially available lipases taught by the Sigma catalog as the lipase to use for the reaction disclosed by Friedrich as these are easily available and well characterized.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652